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EXAMINER

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 21

Application Number: 09/392,243
Filing Date: September 09, 1999
Appellant(s): LEE ET AL.

Philip F. Fox
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 6, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is
contained in the brief.

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(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 21-27 and 36-54 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,607,840	Van Gorp et al	3-1997
4,145,451	Oles	3-1979
4,438,100	Balslev et al	3-1984

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(a) Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is confusing, and therefore indefinite. It is confusing what claim 42 recites because the claim initially recites addition of a peroxide-containing compound to a composition, but then recites that the added product must become undetectable when the amount of added product is measured. It is therefore unclear how much peroxide-containing product can be added, if any.

(b) Claims 21-27 and 36-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Gorp et al (U.S. Pat. 5,607,840) in view of Balslev et al (U.S. Pat. 4,438,100) and Oles (U.S. Pat. 4,145,451).

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Van Gorp discloses a process wherein a mucosal protein hydrolysate is added to protein-containing food or feed. Van Gorp also discloses the preservation of the mucosa starting material using well known preservatives. See col. 4, lines 17-34 and 45-50. Note specifically Van Gorp's disclosure of the suitability of a heating step in the preservation methods as recited in applicant's claims 24, 43 and 44. Note further that because it contains the same material, mucosa, Van Gorp's preserved product would inherently have the same ash amount as recited in the claims.

Van Gorp differs from the claims in that Van Gorp does not use the claimed peroxide or phosphoric acid as a preservative. However, each of Oles (see, e.g., abstract) and Balslev (see, e.g., abstract) make it clear that both phosphoric acid and peroxide were well known preservatives in food and/or pharmaceutical applications. Thus, the claimed substitution of well known preservatives for those used in Van Gorp must be considered an obvious substitution of one known equivalent preservative for another. That is, because the artisan of ordinary skill at the time of applicant's invention would have had a reasonable expectation from Oles and Balslev that phosphoric acid and/or peroxide would have functioned equivalently to the preservatives disclosed by Van Gorp, the

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artisan of ordinary skill would have been motivated to have substituted Oles' phosphoric acid and/or Balslev's peroxide for the preservatives disclosed by Van Gorp.

It is noted that Van Gorp does not disclose the bacterial count of the preserved mucosa product, as recited in applicant's claims 26 and 27. However, because the entire objective of adding preservatives according to Van Gorp's disclosure is the prevention of bacterial growth in the mucosa products, it is respectfully submitted that the determination of an acceptable degree of preservation as measured by bacterial contamination would have been a matter of routine optimization on the part of the artisan of ordinary skill, the degree of bacterial contamination clearly being a result-effective parameter optimized by adding more or less preservative agent. Thus, absent some demonstration of an unexpected result inhering from the claimed process, a holding of obviousness under § 103(a) is clearly required.

(11) Response to Argument

(a) Argument regarding obviousness:

Appellant argues initially that because the references are not directed to relevant art areas, and because evidence has been adduced (Exhibit D, Jay, James M., *Modern Food Microbiology*, page 259-296) to demonstrate that most

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preservatives have only very specific food applications and must be very carefully matched, the disclosures of the cited references can only be combined through improper hindsight. Brief, pages 10-14, 19-23, 30-35.

Appellant is simply inaccurate in stating that the food and pharmaceutical arts are not relevant to the preservation of proteins prior to hydrolysis. The Van Gorp patent is clearly directed to hydrolysis of proteins, and discusses techniques, including the use of preservatives, for preserving the raw material prior to hydrolysis. See column 4, lines 17-50. Van Gorp also states, very explicitly, that the protein hydrolysate produced therein has food and medicinal applications. See column 2, lines 46-59:

Nutritional uses of the protein hydrolysate of this invention include specialty feeds as milk replacers for calf, piglet and other weaning mammals; protein extender for animal feed; and as an amino acid supplement, flavor or protein enhancer for human and pet food. * * * Medicine to which this invention may be applied includes total parenteral nutrition, peritoneal dialysis fluid as an alternative to glucose, and as a protein extender in enteral nutrition.

Thus, appellant's argument, that the food and pharmaceutical arts are not relevant to the preservation of proteins prior to hydrolysis, entirely ignores the plain disclosure of the reference. In view of the fact that Van

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Gorp's protein hydrolysate products are in fact ultimately intended for food and/or pharmaceutical use, one of ordinary skill in the art clearly would have been motivated to look to references disclosing preservatives useful in food and/or pharmaceutical applications, such as Oles and/or Balslev.

Regarding the particularity alleged by appellant with respect to food preservatives and their applications, as evidenced by Exhibit D, it is noted that certain food preservatives are applied more in certain situations than in others. However, reference to Table 11-1 on page 261 of Exhibit D, for example, demonstrates that food-preserving agents generally have very broad utility with a number of varying applications. For example propionic acid/propionates, sorbic acid/sorbates, and benzoic acid/benzoates all are useful in multiple applications of different food types. Thus, contrary to appellant's argument, given the broad applicability of known preservative agents, on the current record it is clear that matching a known acidic preservative agent, such as the claimed phosphoric acid, with a particular application would have been considered a routine matter by the artisan of ordinary skill, as evidenced by Exhibit D.

Appellant further argues, citing *In re Mills* 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990), that no motivation has been

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provided for combining the cited references, and that the mere possibility of combining references is insufficient for a holding of obviousness. Brief, pages 14, 15, 36. However, ample motivation exists in the prior art for using phosphoric acid or peroxide in as preservatives for mucosa. As discussed above, Van Gorp clearly discloses the suitability of adding preservatives to mucosa. See Van Gorp at column 4, lines 17-50. The artisan of ordinary skill, recognizing that Van Gorp's products were ultimately intended for food and medicinal applications, clearly would have considered it obvious to use preservatives known to be useful in food and medicinal applications, such as the phosphoric acid and peroxide disclosed by Oles and Balslev. The motivation for this practice is the recognition in the art of the suitability of the products in the prior art applications. Simply put, applicant's claims recite the use of phosphoric acid and peroxide in an art-recognized manner. The claims are therefore obvious.

Moreover, appellant's excessively narrow reading of *Mills* would effectively eliminate any application of the law of obviousness. Contrary to applicant's argument, a long line of established case law makes it clear that art-recognized suitability of a specific utility for a product renders that use obvious. See MPEP § 2144.07 (entitled "Art Recognized

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Suitability for an Intended Purpose") and the cases cited therein. While appellant appears to assert that the artisan of ordinary skill would consider only those preservatives listed in Van Gorp as being suitable in Van Gorp's stabilization methods, appellant is reminded that the rejection at issue is made under § 103(a), not § 102. Thus, the issue is not whether Van Gorp describes the use of phosphoric acid or peroxide as preservatives. Rather, the issue is whether Van Gorp suggests the use of phosphoric acid or peroxide, preservatives known in the art to be useful in food and/or medicinal applications, as preservatives for mucosa. In view of the prior art's recognition of the clear suitability of phosphoric and peroxide in the type of application disclosed in Van Gorp, the claimed process is properly considered obvious under § 103(a).

Appellant further argues that because Oles uses a synergistic combination of phosphoric acid and acetic acid as a preservative, the preservative agent in Oles has been mischaracterized. Brief, pages 15, 16, 36-38. Appellant further argues that because claim 21 recites only hydrogen peroxide and phosphoric acid in the Markush group listing suitable preservatives, and because Oles uses the "synergistic" combination of phosphoric acid and acetic acid as preservative agents, Oles does not suggest the claimed process. Brief, pages

15, 16, However, this argument ignores the fact that the process is recited in open "comprising" language which encompasses the addition of anything to the composition, including the acetic acid disclosed in Oles. While the claims clearly require that hydrogen peroxide or phosphoric acid be added to the mucosa, they do not exclude the addition of other ingredients, such as Oles' acetic acid. Thus, appellant's argument ignores the actual limitations present in the claims.

Appellant further argues, apparently for the first time during prosecution, that Van Gorp teaches away from the use of peroxide as a preservative because Van Gorp teaches that oxygen scavengers are useful preservatives, whereas peroxide is disclosed by Balslev as an oxidizing agent. Brief, pages 16, 24. However, review of Van Gorp makes it clear that a number of preservatives which clearly are not oxygen scavengers are suitable for use as a preservative. See Van Gorp at column 4; lines 17-50. Van Gorp simply states that the mucosa should be "treated by physical or chemical means to inhibit bacterial growth." Column 4, lines 18 and 19. There is nothing in Van Gorp suggesting that any particular means of inhibiting bacterial growth should be avoided. Rather, by contacting the mucosa with phosphoric acid or peroxide, applicant has done exactly what Van Gorp suggests -- "treated by . . . chemical

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means to inhibit bacterial growth." This argument does not demonstrate non-obviousness.

Appellant further argues that because Balslev discloses that hydrogen peroxide is effective at eliminating mucine-decomposing enzymatic activity, Balslev teaches away from substituting hydrogen peroxide for Van Gorp's oxygen-scavenging preservatives. Brief, pages 16, 17, 24, 25. However, appellant's analysis does not recognize the fact that hydrogen peroxide continuously decomposes, eventually to a concentration of zero, after addition as a preservative to a composition. See Balslev at col. 6, lines 39-68:

Thus it is characteristic to the sterilization and preservation with these oxidizing bactericides that the relatively high initial concentration thereof used in the sterilization process decreases rapidly during the initial short period whereafter a physiologically tolerable, but still bactericidally effective concentration is retained during the following storage and application period.

Thus, rather than teaching away from using peroxide, Balslev's disclosure makes it clear that peroxide is an ideal sterilizing and preservative agent for storage applications, such as Van Gorp's, because of its property of decomposition over time. Moreover, given the fact that it will decompose during storage, the artisan of ordinary skill would not expect the amount of peroxide remaining after storage to affect the

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mucosa-hydrolyzing enzymes used in Van Gorp, contrary to applicant's argument. Further still, appellant fails to provide any direct evidence suggesting that using Balslev's amounts of hydrogen peroxide to sterilize Van Gorp's mucosa compositions will in fact inhibit Van Gorp's process.

Appellant further argues that Van Gorp "teaches away" from both heating and adding preservative materials to mucosa, because Van Gorp discloses that one may treat the mucosa tissue by physical "or" chemical means to inhibit bacterial growth (Van Gorp, column 4, lines 17-19). Brief, pages 17, 18, 26, 27, First, it is noted that only dependent claims 24, 43, 44 recite a heating step. Thus appellant's argument is irrelevant to the patentability of any pending claim other than claims 24, 43 and 44. To the extent relevant, appellant's assessment that the heating and preservative addition steps of Van Gorp are mutually exclusive is incorrect. By disclosing that either heating or preservative addition is suitable to ensure low microorganism counts in the mucosa preparations, Van Gorp clearly provides a reasonable expectation that using both methods will provide a beneficial result as well, thereby rendering such a practice obvious. Thus, the artisan of ordinary skill seeking to be doubly sure of bacterial elimination would have been motivated to have used both methods of bacterial elimination. Note that

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these methods of spoilage prevention^{on} are extremely well known and extremely old in the art of preservation. Thus, claims 24, 43 and 44 are properly considered obvious under § 103(a).

Appellant further argues that claims 48-50 recite protein-derived hydrolysis process steps not disclosed by any of the cited references. Brief, pages 28-30. Appellant's argument regarding Van Gorp's failure to disclose hydrolysis of the mucosa ignores the plain disclosure of the reference. The title of the Van Gorp patent is "Protein Hydrolysate Derived From Mucosa Tissue." The abstract states that mucosa tissue is hydrolyzed with a proteolytic enzyme. Enzymes are protein-containing materials. Because the claimed starting material is contacted with the claimed treating agent, the result, reduction of enzymatic activity, must necessarily be the same. If the result is not the same, the difference must be due to some aspect not currently recited in the claims. Moreover, it is clear from Van Gorp's disclosure (see, e.g. Examples 1-3 at columns 6-8) that the enzymatic hydrolysis is performed after the preservation step, as recited in the claims. Thus, because the enzymatic treatment in Van Gorp follows the step of adding preservative, Van Gorp clearly discloses the hydrolysis steps recited in claims 48-50, contrary to applicant's argument.

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In sum, appellant has, at bottom, done nothing more than use known preservatives in a setting where preservatives were known to be desirable. Each of the ingredients recited in the claimed process is used exactly for the purpose disclosed in the prior art. Because applicant has failed to demonstrate any unexpected result with respect to the claimed combination of ingredients, the holding of *prima facie* obviousness is clearly required.

(b) Argument regarding indefiniteness.

Lastly, appellant argues that claim 42 is definite because one of ordinary skill would be able to determine the metes and bounds of the claimed subject matter, with the understanding that immediately upon adding peroxide to the mucosa, a chemical reaction occurs whereby the peroxide becomes undetectable. Appellant's argument does not demonstrate error. It is simply unclear how peroxide, once added, could disappear completely, immediately upon addition. While appellant alleges an art-recognized understanding regarding an instantaneous chemical reaction, it is not clear what this reaction would be.

The art clearly recognizes the dissipation of peroxide over time. See Balslev, col. 6, lines 39-68. However, Balslev clearly discloses that some peroxide remains present, even after

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extended periods of time. See id. Thus, applicant's argument is simply not in accord with the state of the art. The skilled artisan simply would not find it clear how to add a chemical, yet be unable to detect its presence immediately. In short, the claim makes no sense. Absent some recitation of an amount of peroxide added, and a time after addition at which peroxide is undetectable, the claim is properly considered indefinite.

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For the reasons above, it is believed that the rejections should be sustained.

Respectfully submitted,



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February 26, 2003

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